GEM 4000
Critical Care Analyser

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Point of Care Testing User Training Plan

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Obtaining further supplies

GEM analyser packs	Contact Chemical Pathology
CVP material	
Printer Paper	
Capillary Tubes (Not Labour Suite)	

Contacts & Telephone Numbers

Chemical Pathology	2733 or 2673
POCT Co-ordinator	2733 or 2673

Your Link Nurse is: _____

Introduction

Designed to help you

This booklet has been compiled by the Chemical Pathology laboratory at BHNFT to help you, the healthcare professional, achieve consistently reliable and accurate results.

The different sections of the booklet cover aspects of working with the GEM 4000 analyser including instructions on the routine use, maintenance, troubleshooting and quality control of the analyser. On completing this training all users of the instrument should be able to:

- Analyse all types of sample obtaining accurate results whilst minimising risk to themselves and patients.
- Recognise and act on error messages.
- Look up patient results

Nursing staff should also be able to:

- Change reagent packs and run CVP samples.
- Be aware of Quality Control procedures.
- Change the instruments paper
- Clean the instrument.

Further information can be seen in the SOP available within Chemical Pathology. However, if you have any queries please don't hesitate to contact your Link Nurse or the Chemical Pathology laboratory.

The purpose of this booklet is to provide you with the information you need to achieve accurate results. Thus providing the best quality care for your patients

Staff Responsibilities

Clinical Laboratory Accreditation Ltd (CPA) requires all Clinical Biochemistry/Chemical Pathology Laboratories to guarantee that all Point of Care Testing (POCT) within the Trust is performed to the same standard as required in the laboratory and, in doing so, ensures the safety of patients and staff.

The use of analysers by untrained staff, without adequate management supervision of the equipment and without the use of quality control procedures, can lead to misleading results, adversely affecting the treatment of patients[1].

- **A management or therapeutic decision based on an unreliable result could be fatal.**
- **Getting it right first time is important**

Recommendations

- All staff who perform sample analysis must be properly trained to use the equipment*.
- Untrained or insufficiently trained staff should not use the equipment.
- Quality control checks should form part of the maintenance routine, with the Clinical Biochemistry laboratory directly involved.
- Quality control procedures should aim particularly at maintaining the competence of all equipment users and ensuring the reliability of the results obtained.

The above recommendations are contained within the Department of Health Hazard Notice pertaining to blood glucose measurement but apply equally to any Point of Care Testing.

*As such, it is extremely important that staff are properly trained in the use of the GEM 4000 analyser. The equipment will be password protected and staff will be issued with a password only after they have undergone recognised training and obtained a certificate of competence. If in doubt please contact your Link Nurse or Chemical Pathology before using the equipment.

Remember – an incorrect result could lead to serious consequences for the patient in your care.

[1] Source: Blood glucose measurements: Reliability of results produced in extra-laboratory areas. Department of Health [HN [hazard] (87) 13]

Protocol for the use of the GEM 4000 analyser

This protocol relates to the responsibility of all staff designated to use the GEM 4000 analyser.

1. Follow the manufacturer's guidelines and hospital policy on POCT.

2. Only staff who have received appropriate training may use the analyser.

3. Each member of staff takes responsibility for the quality of the results obtained by him/herself using the following procedures:
   - CVP (Calibration Validation Product) ampoules must be run on changing a reagent pack.
   - If any parameter fails the Intelligent Quality Management procedures (iQM) patient results for that parameter **MUST NOT** be acted upon.
   - Full patient details must be entered into the analyser for every analysis performed (refer to data collection procedure).

4. A nurse for each ward / department should be designated to ensure that equipment is correctly maintained.

5. The department must be enrolled in an external quality control scheme.

6. Unexpected results **MUST** be confirmed by sending the appropriate sample to Chemical Pathology
• Blood gas confirmation requires an arterial blood gas sample.
• Electrolyte confirmation requires a brown top gel tube.

7. Results **MUST** be confirmed by sending a brown top gel tube to Chemical Pathology if they meet the following criteria:
• Sodium <130 or >155 mmol/L
• Potassium <3.0 or >6.0 mmol/L
• Glucose <3.0 or >20.0 mmol/L

N.B. Sodium, Potassium and Glucose are performed on whole blood on the GEM4000 whereas the laboratory analyse serum. Please note there may be a difference between the results

Data Collection

Accurate patient identification is essential to minimise clinical risk and to maintain pathology electronic patient records. To ensure this the following procedure MUST be followed:

GEM 4000

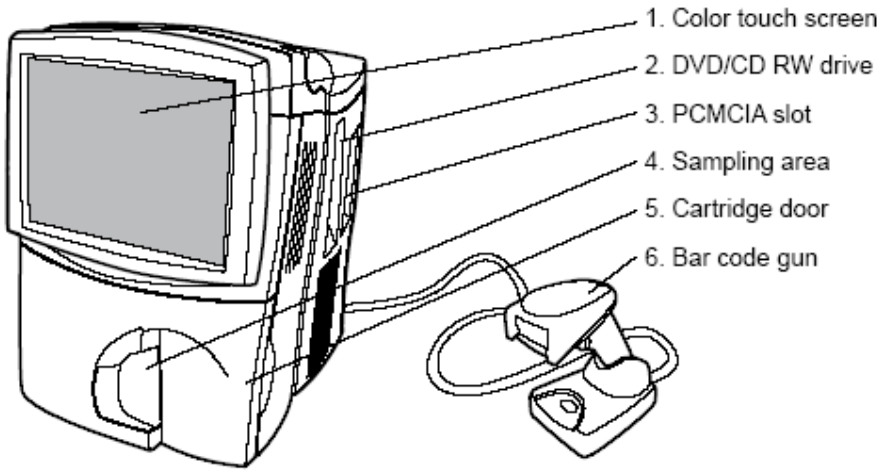
After initiating sampling procedure:

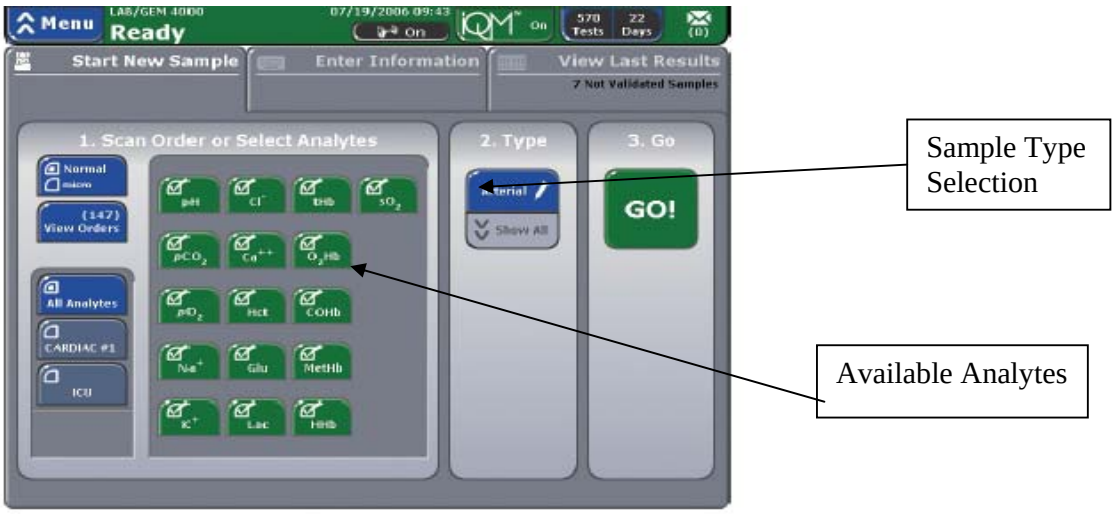
- Input the Patient Unit number*, A/E number or, if this is not available, use the surname and Date of Birth 'ENTER'
- Select and Enter the Surname*
- Select and enter First Name*
- Select and enter date of birth*

* All these are mandatory data items and must be entered before analysis can be completed.

N.B. This information will be used to create a request on the pathology computer system. All Blood Gas analysers are interfaced directly to the Pathology computer system; the results and demographics received by the system from the analysers automatically register and record these results prior to presenting them to the ward reporting system. The interface is set up to trap mis-matched data and prevent this passing to the computer system, the more information entered the more secure the system. **A unit number or name alone is not acceptable.** As there is only a short lag period between the gas being performed and it appearing on the ward reporting system please inform the laboratory immediately if you enter the details for a wrong patient.

The GEM 4000 Analyser





Start New Sample Tab (Home Page)

The Status Bar along the top of the screen provides quick access to critical information and capabilities.

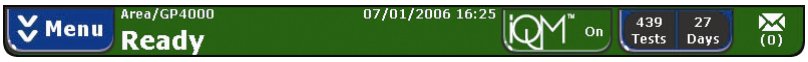
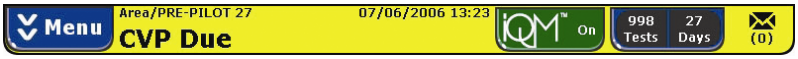
- Menu – Touching the blue Menu button in the upper left triggers a drop-down menu that provides fast access to other functionality beyond patient sampling.
- Analyzer Status – indicates overall readiness of analyzer for patient sampling; it will turn yellow if a specific action (e.g., CVP testing) is needed.
- Date/Time – system clock runs on 24 hour time.
- iQM On Button – iQM is Instrumentation Laboratory's patented Intelligent Quality Management software, which ensures the integrity of the overall analysis system. Quality testing runs automatically in the background.
- Tests/days Button – these figures indicate how many days/tests remain before you must change the cartridge. Selecting this button will display the exact day/time the cartridge will expire. When either 2 days or 20 tests are reached, the button background color will turn yellow.
- Mail Button – alerts you to incoming e-mail messages (if the system is attached to a network) and system error messages.

Sample Preparation

Prior to analysis, it is essential that the sample be thoroughly mixed. Hematocrit, total hemoglobin, hemoglobin derivatives, and oxygen are particularly affected when samples are not well mixed. A uniform distribution of red blood cells and plasma prior to sample aspiration is mandatory for reliable results. The sample should be inverted at least 3 times and rolled between outstretched palms at least 5 times if drawn within 5 minutes of sampling. The syringe should be gently rotated for a minimum of 2 minutes immediately prior to analysis if more than 5 minutes have elapsed from sample collection.
Capillary tube samples should be remixed if more than 5 minutes have elapsed since collection by mixing the capillary tube between outstretched palms for at least 5 seconds.

Assaying a Patient sample

Sample types which can be used on the GEM 4000 are whole blood and fluids. Remember when processing fluids to be aware that gelatinous samples or samples containing a lot of debris may block the probe and it may be better to sent them to laboratories for processing.
Before any sample is introduced always check that all the analytes on the Gem are highlighted green and showing no errors. If this is not the case perform the necessary maintenance.
Any analytes not highlighted in green will not give a result.
Any results marked with question marks are unreliable

green	Fully operational or normal
	
yellow	Conditional state, awaiting specific action
	
red	Stopped or non-functional
grey/shaded	Functionality unavailable or not selected

- Select Normal or Micro sample by pressing the Normal/Micro toggle button on the left. Micro sampling is available only with capillary tubes.
  Sample volumes Full profile and CO-OX 150 µL
  Full Profile 95µL
  Micro Mode 65µL
- Select the sample type/container combination using the drop-down menu under *2. Type*, if it is not already selected.
- Alternatively select the required profile from the right hand side of the screen, this will select the sample type automatically.
- Press **GO!** The sampler will emerge from its home position.
- **Syringe or ampoule sampling** – The sampler will extend from the luer and move approximately 30 degrees from its home position. Push out a few drops of the sample onto a tissue to ensure there is no clot in the syringe tip.
  Present the syringe or ampoule by placing it over the end of the sampler. The sampler should be inserted far enough into the container to allow sufficient sample to be aspirated but not so far that the sampler touches the bottom of the device.

- **Capillary tube** – The luer will present just below the home area (the sampler will not extend). If the blood is not flush with the end of the capillary tube that will be placed into the sampler, gently tilt the tube down so that the blood is flush with the end of the capillary tube prior to placing it into the sampler. Place the end of the capillary tube with the blood flush with the end in the black portion of the sampler. Do not use excessive force. **Hold** the exposed end of the tube, keeping the tube in line with the sampler, and press **OK** to begin aspiration.
- The system will aspirate the sample and beep when aspiration is complete. Remove the container promptly. Select OK to retract the probe (labour suite only). Dispose of the remaining sample into a sharps bin.
- The system will perform analysis while you enter patient information on the Enter Information tab using the alphanumeric keypad (the keypad becomes accessible when you press a button requiring data entry) or barcode gun. Required fields are indicated with an asterisk (*). Sample results cannot be viewed until all required fields have entries made in them. If you ara analysing a sample for another person this can be recorded using the 'Comments' button.
- Select View results to see patient results.
- There are 'Normal Limits' in the analyser for Arterial samples only, any results outside these limits will have up/down arrows on them and be highlighted yellow on screen. No flag may mean no normal range is entered e.g. Glucose. Any result highlighted red is outside the technical limits for the analyser. Technical limits can be obtained from the lab or from the IL User manual.
- When finished select Start new Sample to return to Main Menu.

Finding / Reprinting Previous Results

Each GEM 4000 keeps a record of all samples performed on that analyser; if you wish to look up and/or reprint a previous result:.

- Press the blue **Menu** button in the upper left corner.
- Select **Search Results** from the pull down menu.
- Select the search criteria in the Search Criteria screen.
- These buttons are data entry fields or drop-down menus.
- Date and time frame criteria (lower right-hand corner of screen) are required for all searches

Changing Reagent Packs

As changing the cartridge will result in the analyser being out of operation for approx. 60 minutes it is better to change it during a quiet period and not wait until the pack is totally empty or expired. The GEM Cartridge should also be replaced if there is a problem with IQM on any of the channels. If the pack is empty the cartridge door will automatically open and display a message to the operator to remove the cartridge.
To remove a cartridge prior to its maximum onboard use-life or test capacity, follow the instructions provided below.

- Press the blue **Menu** button in the upper left corner of the screen. Select **Remove Cartridge**.
- Enter your password. As a precaution, the system will ask you whether you want to continue. Press **No** to stop the process and return to the Main Sampling screen. Press **Yes** to continue.
- Once you press **Yes**, the door will click open slightly. Move the door to the left, grasp the cartridge, and pull it gently toward you. Dispose of cartridge in an appropriate biohazard container. The system will now be inactive until you reinsert a new cartridge.
  NOTE: Cartridges cannot be reused once they have been removed.
- Unpack the cartridge from its protective wrapper. Remove the plastic cover from the pump winding area. Discard the protective wrapper and plastic cover.
- Position the cartridge with the grey sampling area facing forward. Push the cartridge in until you feel resistance. Please note that approximately one inch of the cartridge will extend beyond the front of the analyzer.
- Guide the analyzer door to the right to close it and move the cartridge into its final position.
- In approximately 20 seconds, the analyzer will inform you that the cartridge is warming up. The clock will count down for the next 40 minutes as the cartridge warms up. During this time, the sensors will hydrate, and the analyzer will perform internal checks and calibration.

Assay both levels of CVP once warm up is complete.

CVP and iQM

This process ensures the integrity of the new cartridge and the overall analysis system, providing a clear baseline for operation. It is only necessary to perform CVP when inserting a new cartridge. Testing will require approximately 3 minutes per ampoule to complete
The analyzer will inform you that CVP testing is due via the Status Bar along the top of the screen, which will be highlighted in yellow with the words CVP Due prominently displayed. You will be unable to report patient results for an analyte until CVP testing is successfully completed for that analyte.

- Press GO! to begin sampling.
- Select an ampoule from the choices on the screen or scan the 2D bar code on the ampoule label using the bar code gun. Press OK to begin CVP testing. There is no specific order to do the CVP.
- Immediately prior to use, hold the ampoule by the top, above the break line, and shake vigorously for approximately 10 seconds.
  NB: Hold the ampoule only above the break line. Holding the ampoule in your hand will cause the aqueous solution to exceed the recommended testing temperature and can adversely affect CVP results.
- Gently tap the ampoule so the liquid settles back to the bottom.
- Carefully snap open the ampoule.
- NOTE: Aspirate samples immediately after opening. Any delay in measuring may cause room air contamination and result in lower pCO_2 and higher pO_2 values than stated in the insert.
- Present the opened CVP ampoule to the sampler, which will emerge from the grey sampling area at the front of the analyzer. Hold the ampoule so the

sampler is immersed in the CVP solution, but the so that the end of the sampler does not touch the bottom. Press OK to begin aspiration. The analyzer will issue an audio prompt when it has aspirated enough of the CVP sampling solution (approximately 170 µL). Remove the ampoule immediately upon hearing the audio prompt and select OK to retract the probe. Dispose of the rest of the ampoule in a Sharps bin. See CVP Sample Results on how to process results.

Analyte buttons will continue to be shown in red to indicate that CVP testing is not complete. The analyzer will direct you to continue sampling the remaining ampoules. As you continue with the CVP sampling process, more of the analyte selection buttons will turn green, indicating that testing is proceeding correctly.
When you complete CVP sampling, you will see the Start New Sample tab, with all of the analyte selection buttons shown green and the upper Status Bar indicating Ready. You are now ready to begin patient sampling

CVP Sample Results

All results within range will be indicated in green text with a white background; out-of-range in white text on a red background.
If all results **are within range, press Accept**.
In the event of **an out-of-range result:**

- **Exclude** the sample.
- Run a full calibration by selecting Menu > Diagnostics > Run IQM Process.
- Repeat the analysis with a new vial. Do not sample with the original ampoule
- If analytes that failed the acceptable range the first time fail again, do not use the cartridge*.
- If the original analytes that failed pass, but analytes that passed the first time fail on the second vial, run a third new vial. You will once again be prompted to run a full calibration before repeating the process.
- If any analytes fail following the third attempt and that analyte is crucial, do not use the cartridge*. Insert a new cartridge and start again.

*If any analytes fail following the second/ third attempt and that analyte is not crucial e.g. Glucose, you can Accept the CVP and run the pack without the analyte. You can retry the CVP at a later time. The decision as to if this is a possible solution as opposed to trying a new pack is down to individual wards.

Internal Quality Control Scheme

Intelligent Quality Management (iQM®) is used as the quality control and assessment system for the GEM Premier 4000 analyzer. Once the cartridge calibration is verified, the internal iQM Process Control solutions, internal checks and software pattern recognition monitor the status of the system during the cartridge use life. If this process detects an error on a sensor it will deactivate that sensor showing the analyte on the screen as grey with 'fixing' written underneath. It is possible to use the analyser at this time but no result will be given for that analyte. If the iQM process is unable to 'fix' the sensor the analyte will be permanently disabled and will show as grey with 'iQM disabled' written in Red on the screen. It is possible to continue to use the analyser at this time but no result will be given for that analyte.
A more in depth description of IQM can be found in the GEM 4000 Reference Guide.

External Quality Control Scheme

Every analyte assayed on the IL gas analyser must be entered in at least one Accredited External Q.A. scheme.
Blood gas parameters are entered in the WEQAS Blood Gas scheme.

- The Chemical Pathology Department will send out the external QC samples once a month.
- There are no 'expected' values for the external QC samples.
- The sample is prepared according to WEQAS instructions and is run as a proficiency sample.
- The results must be recorded on the sheet of paper accompanying the sample.

This sheet must be returned to Chemical Pathology who will forward it to WEQAS.

Analysing External Quality Control Samples

- Select Proficiency sample type and press GO to start sampling.
- Select the Blood Gas Profile.
- Select an ampoule and hold by the top, above the break line. Shake vigorously for approximately 10 seconds.
- Gently tap the ampoule so the liquid settles back to the bottom.
- Carefully snap open the ampoule.

NOTE: Aspirate samples immediately after opening. Any delay in measuring may cause room air contamination and result in lower pCO_2 and higher pO_2 values than stated in the insert.

- Present the opened ampoule to the sampler, which will emerge from the grey sampling area at the front of the analyzer. Hold the ampoule so the sampler is immersed in the QC solution, but the so that the end of the sampler does not touch the bottom. Press OK to begin aspiration. The analyzer will issue an audio prompt when it has aspirated enough of the solution. Remove the ampoule immediately upon hearing the audio prompt (Labour Suite should select OK to retract the probe). Dispose of the rest of the ampoule in a Sharps bin.
- The system will perform analysis while you enter the information on the Material Information tab. Enter the distribution number, sample number (can be found on the results sheet), e.g. 159,1.
- Select View results to see results.
- When finished select Start new Sample to return to Main Menu.

Remember to write the results on the return sheet and send to the laboratory.

Cleaning

The GEM 4000 analyser requires very little maintenance however it is essential that it be kept clean at all times.

- Clean Analyser: Wipe with soapy water or 10% chlorine bleach solution.
- Clean touch screen. Carefully wipe the face of the touch screen free of fingerprints and other smudges using a soft cloth moistened with water.

Changing Paper

To install the thermal printer paper in the paper area on top of the system:

- Press the tab at the top of the system to release the door.
- Open the door and extend paper guide if desired.
- Place the roll of paper in the compartment so the paper unfurls from the bottom.
- Press the door firmly closed.

NOTE: The thermal paper can only be printed on one side.

Health and Safety

There is a minimal risk in using the Gem (see appendix 1) as long as gloves and protective clothing are worn.
Departmental policy should be followed when dealing with a blood spillage.

Troubleshooting

Faults on the GEM 4000 can be narrowed down to pack problems or hardware problems. This makes troubleshooting straight forward. Change the pack or if this fails to resolve the problem then call Chemical Pathology.

If there is a persistent error on one or more analytes or if the pack is blocked due to clots it may be necessary to change the pack. Follow the procedure outlined earlier BUT inform Chemical Pathology as soon as possible so that the pack data can be obtained and sent to I.L. for analysis. If changing the pack does not alleviate the problems then it is likely to be faulty hardware. In this instance inform Chemical Pathology as soon as possible so that a replacement GEM 4000 can be supplied.

Appendix 1 Risk Assessment

Details Of Process

An automated analyser for use with patient whole blood.

Chemicals To Be Used and Hazards

None

Other Hazards

Patient material: Infectious material
Mechanical: Moving sample probe.
Electrical: Electric shock.
CVP: None

Control Measures Required

- Proper training and supervision.
- Installation and maintenance of equipment as defined by Health Authority policy.
- All spillages must be dealt with as by ward/department policy
- Fire precautions must be observed as ward / department policy

Disposal Methods

- All biological materials and contaminated waste materials must be discarded into appropriate bins for incineration
- Sharps to be disposed of into 'SHARPSAFE' bins.

Assessment Of Staff Exposure

SIGNIFICANT RISK OF INFECTION FROM PATIENT MATERIAL.
MINIMAL RISK FROM ELECTRICAL AND MECHANICAL HAZARDS
ADHERENCE TO THE CONTROL MEASURES ABOVE SHOULD BE ADEQUATE IN CONTROLLING THE RISK.

ASSESSMENT: MINIMAL